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(54) Oxygen-generating surgical dressing

(57) A storable topical wound dressing which generates gaseous oxygen in contact with a wound over a sustained period of time contains or is coated with a composition of a peroxy compound (eg. hydrogen peroxide or a percarbonate) and an agent for activating the peroxy compound to decompose to evolve oxygen (eg. potassium iodide), the agent being liberated when the dressing is applied to a wound. The per-oxy compound may be absorbed in a hydrocolloid polymer sheet, and the activator may be absorbed in a similar overlying sheet or contained in rupturable means attached to the polymer sheet.

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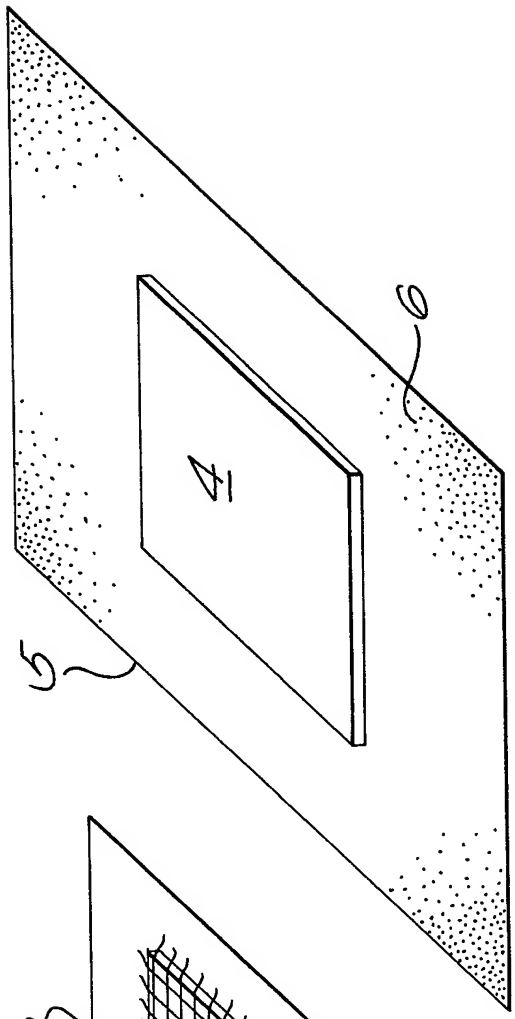

Fig. 2.

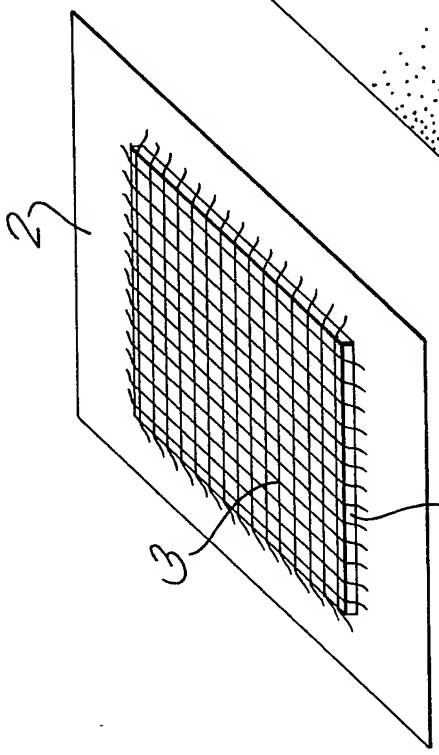

Fig. 1.

SPECIFICATION

Surgical dressing

The invention relates to surgical dressing for protecting wounds and for promoting the healing process.

The first tissue to cross the surface of a healing wound is the epithelium, which begins with rapid migration of epithelial cells from the wound edges and from the upper transected ends of sebaceous and sweat gland ducts and hair follicles. Only after the epithelium has grown across the incision, and thereby separated the underlying exposed dermis from the air, do recognisable changes commence within the depth of the wound. The rate of re-epithelialisation of a wound is a convenient measurement of the rate of wound healing, for when the new epithelium has completely grown across the wound surface, that wound can be said to be 'healed'.

Skin cells require oxygen to live and proliferate, and at the site of a wound, where cell division and migration are both much more rapid than normal, the requirement for oxygen is particularly high. The supply of oxygen—necessary for the synthesis of adenosine triphosphate within the cells—is often found to be the rate-determining factor in wound healing. It has been shown, for example, that standardised partial thickness wounds on pigs epithelialise at a rate 30 per cent greater than in controls, when the pigs are treated with pure oxygen at 2.0 atmospheres absolute pressure for one third of the total time of the experiment. G.D. Winter and D.J.D. Perrins, in "Proceedings of the Fourth International Congress on Hyperbaric Medicine", p.363 Tokyo, 1970, have suggested that hyperbaric oxygen therapy raises the oxygen tension in the neighbourhood of the regenerating epidermis and this enables the epidermal cells to move more rapidly than they normally do. In corroboration of this, measurement of the oxygen tension in wounds shows this to be much lower than in normal tissue, especially during the process of epithelialisation (I.S. Silver, Prog. Post. Res) 1969) *3*, 124).

Covering the wound surface more quickly with new epithelium inhibits excessive growth of underlying connective tissue. This has the effect, therefore, of minimising the residual scar, especially in those wounds which are of partial thickness, i.e. those in which the underlying muscle tissue is not damages —which constitute the majority of wounds.

Not only is it generally impracticable to treat injured persons in oxygen chambers, but this might not even be particularly effective if there is any defect in the vascular system in the vicinity of the wound. This consideration would be particularly relevant in the case of burns, in which the heat has coagulated the blood capillaries to a certain depth surrounding the wound. Similarly, wounds such as varicose ulcers are very poorly supplied with systemic oxygen because the patient's circulation is very poor in that region.

For the reasons both of convenience and the effective delivery of oxygen to the required site it is therefore desirable to provide a topically applied hyeperbaric oxygen dressing.

It is known (Canadian Medical Association Journal, *115*, 4th December 1976, pp. 1101–1106) that benzoyl peroxide applied topically on a dressing to a cutaneous ulcer apparently shortens the healing time, the effect being thought to be due to slow sustained release of oxygen by benzoyl peroxide. Benzoyl peroxide as such is, however, not amenable to the production of reliable, ready-made, possible pre-packaged hyperbaric oxygen dressings which could be stored until required for use, since it loses substantial proportions of oxygen spontaneously.

According to the invention we provide a storage topical wound dressing capable of generating gaseous oxygen in contact with the wound in a sustained manner for a period of time, subject to activation by an applied agent. In respect of the activating agent to be applied, it is convenient to generate the oxygen in chemical decomposition or by electrolytic decomposition. In particular, it is convenient to generate the oxygen by decomposition of a per-oxy compound by an initiator, provided that the per-oxy compound is sufficiently stable under ambient conditions before activation and its decomposition rate can be controlled to allow production of oxygen over a reasonable period of time such as 24 hours. By per-oxy compounds we refer in particular to hydrogen peroxide and compounds such as the percarbonates, stabilised if necessary.

In one embodiment of the invention the control of reaction rate is achieved by absorbing the per-oxy compound and the initiator into absorbent materials where diffusion of the peroxide and initiator to an interface between them becomes the rate-determining step. In particular, we propose the use of a hydrocolloid polymer, in particular a sheet of crosslinked poly(2-methacryloyloxyethyl trimethyl ammonium methosulphate) as absorbent carrier. Control of the molecular weight of the polymer and the crosslink density in turn controls the diffusion rates of absorbed materials through the polymer.

Regarding the initiator, many compounds will cause the decomposition of per-oxy compounds, and these are well known from the literature. It is particularly convenient in this application to use potassium iodide as the initiator, firstly because it is a relatively weak initiator and secondly because the decomposition product is iodine and there is thus a colour reaction to show that the reaction is

proceeding. Other initiators may be used.

In use, it is necessary to bring the peroxide and initiator together to start the reaction.

In one embodiment an activatable dressing is formed by absorbing the per-oxy compound such as hydrogen peroxide, into a sheet of hydrocolloid polymer. One surface of this sheet is protected by a piece of semi-permeable material such as microporous polypropylene which allows the passage of oxygen but is substantially impermeable to liquids. The other surface of the sheet may be protected by a piece of material which allows the passage of both gases and liquids. This composite sheet is to be applied as the primary dressing on the wound and may be cut to an appropriate size.

To provide an activating agent, a secondary dressing is formed by absorbing an aqueous solution of an initiator such as potassium iodide into a sheet of hydrocolloid material of approximately the same size as the primary dressing, and one surface of this sheet is covered with a larger sheet of impermeable pressure sensitive adhesive coated material.

In use the primary dressing is applied to the wound, the semi-permeable material being next to the wound, and the secondary dressing is applied over the primary dressing, and stuck down all round the wound area. This operation brings the hydrocolloid polymer sheets into close contact and oxygen is produced at the interface where the hydrogen peroxide or other per-oxy compound and the potassium iodide or other initiator diffuse together. Because the wound area is completely covered with an occlusive film, the oxygen can only escape through the semi-permeable sheet and thence on to the wound surface. The diffusion characteristics of the polymer sheets are arranged such that the decomposition is substantially complete in approximately 24 hours.

In another embodiment of the invention, the initiator is supplied as rupturable granules or microcapsules with an inert coating or envelope and is attached to the primary dressing described above. This construction, in discrete pieces of a convenient size, is attached to a continuous strip of occlusive pressure sensitive adhesive material. The whole is supplied in a dispenser, from which it is withdrawn between two rolls or other pressure device which ruptures the inert coating of the initiator, thereby allowing the reaction to start.

In both embodiments, it is convenient to protect the pressure sensitive adhesive material with a release liner before use.

The following Example is given to illustrate the invention and is described with reference to the accompanying drawing in which:–

Figure 1 represents in perspective a view of the back of a first part of a dressing according to the invention, and

Figure 2 represents in perspective a view of the front of a second part of the same dressing.

EXAMPLE

A dressing is prepared consisting of two parts, shown in Figs. 1 and 2 and designated respectively parts (1) and (2). Part (1) is made by taking a sheet of poly(2-methacryloyl oxyethyl trimethyl ammonium methosulphate) (hydrocolloid) $2^m/_m$ in thickness and immersing it in 100 volume hydrogen peroxide for 5 minutes. After this time the hydrocolloid sheet is withdrawn, drained and a square piece 1 measuring 5 × 5 cm is cut therefrom and placed centrally on to a square piece 2 of microporous polypropylene (Van Leer Ltd., West Byfleet, Surrey) measuring 6 × 6 cm. Part (1) is completed by placing on to the top face of the hydrocolloid a square piece 3 of apertured rayon non-woven fabric measuring 5 × 5 cm (Keybak, registered Trade Mark of Johnson and Johnson).

Part (2) of the dressing is made by placing a square piece 4 of $2^m/_m$ thick hydrocolloid sheet measuring 5 × 5 cm centrally and squarely on to the adhesive side of a piece of plasticised polyvinylchloride film 5 measuring 12 × 12 cm coated with an acrylic adhesive 6. On to the exposed face of the hydrocolloid sheet is now painted evenly 0.5 ml of a 10 per cent solution of potassium iodide in water and over the whole of this part of the dressing is placed a piece of silicone release paper (not shown) so as to completely cover the hydrocolloid and the adhesive.

In order to activate the dressing, the silicone release paper is removed from part (2) and the face of part (2) thereby exposed is put into contact with part (1) such that the two pieces of hydrocolloid 1, 4, are separated only by the non-woven fabric 3. Contact between the two pieces of hydrocolloid is made through the apertures in the non-woven fabric and this initiates the oxygen-generating reaction. The whole dressing is now applied to the wound in such a way that the microporous polypropylene 2 is in contact with the wound and the dressing may be secured by means of the adhesive 6 to the skin surrounding the wound. Such a dressing as this will give a slow release of oxygen sustained for a period of about 24 hours.

By "microporous" is meant permeable to gases but impermeable to liquids. Miroporous polypropylene made by Van Leer is an opaque white film having a moisture vapour permeability of about 1000 g/m²/24h.

Suitable hydrocolloid polymer material for use in this invention is described and claimed in our British patent No. 1,524,899.

CLAIMS

1. A storable topical wound dressing capable of generating gaeous oxygen in contact with a wound in a sustained manner for a

period of time subject to activation by an applied agent.

2. A dressing according to Claim 1 capable of generating oxygen by chemical decomposition of an oxygen compound by an initiator therefor as activating agent.

3. A dressing according to Claim 2 comprising a layer of a hydrocolloid polymer sheet containing absorbed therein an oxygen compound capable of releasing oxygen subject to activation.

4. A dressing according to Claim 3 wherein the layer of hydrocolloid polymer sheet is protected by semipermeable facing material on one side and an optional porous backing material on the other side.

5. A dressing according to Claim 3 or 4, having a further layer of a hydrocolloid polymer sheet laid over the first layer of hydrocolloid polymer sheet, said further layer containing absorbed therein an initiator for decomposition of the oxygen compound and having an impermeable backing sheet thereon.

6. A dressing according to Claim 3 or 4 wherein rupturable granules or microcapsules, containing an initiator for decomposition of the oxygen compound and having an inert coating or envelope, are attached to the back of the hydrocolloid polymer sheet and covered by occlusive pressure-sensitive adhesive sheet material.

7. A dressing according to any of Claims 2 to 6 wherein the oxygen compound is a per-oxy compound.

8. A dressing according to Claim 7 wherein the per-oxy compound is hydrogen peroxide.

9. A dressing according to any of Claims 5 to 8 wherein the initiator is potassium iodide.

10. A storable topical wound dressing substantially as described in the foregoing Example.

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